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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,078	12/21/2000	Woodrow C. Monte	32166.00002	2298

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/747,078	Applicant(s) MONTE, WOODROW C.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-46* is/are pending in the application.

4a) Of the above claim(s) *10,12 and 42-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-9, 11, and 13-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on November 12, 2002 in Paper No. 8 wherein claim 1 is cancelled and claims 2-46 have been amended. Currently, claims 2-46 are pending in this application.

This application contains claims 42-46 drawn to an invention nonelected with traverse in Paper No.3 submitted December 6, 2001. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

It is noted that claims 10 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species in Paper No. 6, submitted March 12, 2002.

Applicant's amendment canceling claim 1 filed on November 12, 2002 in Paper No. 8 with respect to the rejection of claim 1 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, of record stated in the Office Action dated May 7, 2002 have been fully considered and found persuasive to remove the rejection as to claim 1.

Applicant's amendment canceling claim 1 filed on November 12, 2002 in Paper No. 8 with respect to the rejection of claim 1 made under 35 U.S.C. 103(a) as being unpatentable over Monte (5,707,843) in view of Monte (5,578.336 and 5,424,299) for

reasons of record stated in the Office Action dated May 7, 2002 have been considered and are found persuasive to remove this particular rejection as to claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9, 11, and 13-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record stated in the Office Action dated May 7, 2002.

Applicant's remarks filed on November 12, 2002 in Paper No. 8 with respect to this rejection of claims 2-9, 11, and 13-41 have been fully considered but are not deemed persuasive for the following reasons. Applicant asserts that "an active" in claim 2 and "another substance" in claim 25, and "a beneficial effect" in claims 2, and "slowly enough" in claim 2, and "a temperature capable of denaturing the active" in claims 2, 5,7, and 25 are defined in the specification at page 1, lines 11-23. However, these expressions are not considered to be clearly defined in the specification, for example, "the term "active" or actives" refers one or more biologically active substances, materials, or constituents". It is unclear what may be considered "biologically active substances, materials, or constituents" employed in the claimed method herein. Therefore, the scope of claims is indefinite as to the method encompassed thereby. Moreover, "the term "beneficial effect" means a measurable desired change to a

composition due to the presence of an active added to the composition" is not considered to be clearly defined in the specification since what may be considered as a measurable desired change to a composition herein.

The expression "slowly enough" in claims 2 is a relative term which renders claims 1-9, 11, and 13-41 indefinite. The expression "slowly enough" is not defined in the specification and claim. It is unclear as to how slow may be considered as slowly enough.

The following is a new rejection necessitated by Applicant's amendment filed on November 12, 2002 in Paper No. 8.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9, 11, and 13-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "the temperature that would denature the active" in claims 2 and 25 render claims 2-9, 11, and 13-41 indefinite since the term "would" is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree as to the certainty of temperature denaturing the active herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-9, 11, and 13-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monte (5,707,843) in view of Monte (5,578.336 and 5,424,299) for reasons of record stated in the Office Action dated May 7, 2002.

The changed language, "a method for including" from "a method for adding" in amended claims 2-9, 11, and 13-41, in Applicant's amendment filed on November 12, 2002 in Paper No. 8, does not render the claimed methods herein nonobvious over the prior art as discussed below.

Monte discloses a method therein including steps: adding (including) an enzyme or lactose-converting enzyme to a composition, heating the composition therein to a temperature at which the enzyme may be denatured, and packaging the enzyme composition, or cooling the enzyme composition. Monte also discloses the lactose enzyme composition therein is a food product such as a milk product. Moreover, Monte discloses that the lactose therein can be converted from 50% to 99% and that the composition has pH of 6.0 or less. See abstract, col.1 lines 21-39, col. 2. lines 7-10 and 18-49, col.5 lines 36-45, and claims 4-5.

Monte does not expressly disclose providing a tablet including the active, the tablet being coated and adding the tablet to the container in the instant claimed method for adding the particular heat-sensitive active material, enzyme. Monte does also not expressly disclose the coating may be sugar and the food may be an enteral food.

Monte (5,578.336) discloses that the coating of the enzyme candy composition therein is sugar or sugarless sweetener. See abstract and col.2 lines 65-67, and Examples.

Monte (5,424,299) discloses that the food containing enzyme composition therein is an enteral food. See abstract, col.1 lines 64-66, Examples and claims 1-9.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a tablet including the active, the tablet being coated and to add the tablet to the container in the instant claimed method for adding the particular heat-sensitive active material, enzyme, and to coat the tablet with sugar and prepare the particular food, an enteral food.

One having ordinary skill in the art at the time the invention was made would have been motivated to provide a tablet including the active, the tablet being coated and to add the tablet to the container in the instant claimed method for adding the particular heat-sensitive active material, enzyme, and to coat the tablet sugar and prepare the particular food, an enteral food, since these steps herein i.e., providing a tablet including the active, the tablet being coated and adding the tablet to the container, and coating the tablet with sugar and preparing the particular food, an enteral food, are considered well in the competence level of an ordinary skilled artisan in the art, involving merely

routine skill in the art. Moreover, these steps are also considered to be conventional steps in pharmaceutical or food science. Further, adding the particular heat-sensitive active material, enzyme, into a composition, coating an enzyme candy composition with sugar and preparing an enteral food containing enzyme composition are known in the art according to Monte.

Thus, the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed on November 12, 2002 in Paper No. 8 with respect to this rejection made under 35 U.S.C. 103(a) in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant argues that "neither Monte nor any of the references of record teach, among other things, including an active, or a device comprising an active, in a composition while the composition is at a temperature that would denature the active". However, as discussed in the previous Office Action, Monte clearly discloses a method therein including steps: adding an enzyme or lactose-converting enzyme to a composition, heating the composition therein to a temperature at which the enzyme may be denatured, and packaging the enzyme composition, or cooling the enzyme composition. Monte also discloses the lactose enzyme composition therein is a food product such as a milk product. Moreover, Monte discloses that the lactose therein can be converted from 50% to 99% and that the composition has pH of 6.0 or less. See

abstract, col.1 lines 21-39, col. 2. lines 7-10 and 18-49, col.5 lines 36-45, and claims 4-5.

Applicant also argues that "some of the benefits of the present invention (page 7,1.15-page 8,1.22), which explain to a large extent of the nonobviouse of the claimed invention". Nevertheless, the instant claims are not limited to "some of the benefits" in the specification. Moreover, this benefits are expected as taught or fairly suggested by Monte (5,707,843). Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c).

The record contains no clear and convincing evidence of nonobviousness or unexpected results for the combination method herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
January 14, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

1/27/03